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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,666	02/11/2004	Tushar Patel	101896-0233	3475
21125 7590 12/31/2008 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604				
EXAMINER PELLEGRINO, BRIAN E				
ART UNIT		PAPER NUMBER		
3738				
NOTIFICATION DATE		DELIVERY MODE		
12/31/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doctet@nutter.com

Office Action Summary

Application No.

10/776,666

Applicant(s)

PATEL ET AL.

Examiner

Brian E. Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-13, 15-26, 28, 29, 31-44, 46-54 and 86-93 is/are pending in the application.
- 4a) Of the above claim(s) 25, 29, 32, 39-44, 47 and 49-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-13, 15-24, 26, 28, 31-38, 46, 48 and 86-93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-846)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/29/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's AF submission filed on 9/2/08 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,3-13,15-24,26,31,33-38,46,48,86-90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1,26,86 recites there are "first and second pathways" extending through guide members. How is there two separate pathways when there is only one channel extending through the guide member? Applicant referred the Examiner to Fig. 5A, but Fig. 5D clearly depicts the recitation of what Applicant is claiming regarding two pathways, by reference numbers 24c' and 26c'. These two pathways share the same space and thus do not define two distinct or separate areas. Because they share the same space and are

aligned on the same axis, they are in essence one pathway and not two. It is ambiguous to recite two pathways, which one of ordinary skill in the art would interpret to mean some different opening or channel. Since they share the same channel, there cannot be two pathways and thus, the claims are indefinite.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 86-90 as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Santangelo (5067477). Fig. 1 shows a guide device with first **14** and second **16** members slidably movable with respect to one another and adapted to be positioned on a spinal plate. It can be seen that there are a plurality of opposing tabs **24** that are substantially C-shaped and is adapted to match the contour of the perimeter of a spinal plate. The guide members also include arbitrary first and second pathways in substantial alignment with a distal portion of each guide member since there is spacing that extends between the tabs from a proximal to distal end of the tabs and would allow a tool to be inserted there between. It can also be construed that there are cutout portions formed in the guide members that provide a holder for the tabs which would retain the plate but allows for visualization of the plate between the guide members.

Claims 91,93 are rejected under 35 U.S.C. 102(b) as being anticipated by Ulrich (DE 4201043). Fig. 6 shows a guide device for use with a spinal fixation plate. The guide device includes first **22'** and second **22"** arms slidably movable with respect to

one another. It can also be seen the arms each include a guide member **21** coupled to the distal end of the arms and have opposed cutout portions in the opposed sidewalls at the distal ends of the guide members. It can be construed since the arms and guide members are positioned adjacent one another the cutout portions, walls and pathways can be interpreted to "oppose" one another. Fig. 5 shows that the cutout portions are adapted to provide visualization of the positioning device that is coupled to the spinal fixation plate. Additionally a single cut-out can include multiple "portions" that together make up an entire or whole cut-out. For example if a circle is cut in half, it has two opposing halves or portions. Thus, it can be said with Ulrich that clearly there are two halves forming two cut-out portions.

Claims 1,3,4,11,15-19,22,23,26,28,31,36,37,46,48,91,93 as best understood, are rejected under 35 U.S.C. 102(e) as being anticipated by Phillips et al. (7147599). Phillips et al. show (Fig. 1) first and second arms **18,20** slidably moveable with respect to one another along a curved elongate support **12**. It can also be seen there are first and second guide members coupled at the distal ends of the arms and have cut-outs formed therein and are adapted to provide visual access. The Examiner is interpreting the "first and second pathways" as best understood to be areas located on opposite sides of where the tooth or pin extends through the central area of the guide member and are in communication with each other as seen in Fig. 1. Regarding claim 91, the examiner is interpreting the claimed elements opposed cut-out portions in this way: since a portion only is part of a whole, clearly a cut-out can arbitrarily have opposed cut-out portions that together form the entire cut-out. Claims in a pending application should

be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054,1055.

Regarding claims 16,28, Fig. 5 shows the distal portion of the arms can extend at an angle with respect to the proximal portion. Regarding claim 22, the first arm can be fixedly mated to the support member, see Fig. 2. With respect to claim 23, it can be seen there is an adjustment mechanism on the proximal end of the second arm to allow movement along the support member.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips et al. '599. Phillips et al. is explained supra. However, Phillips et al. do not disclose a spring lock mechanism that is moveable between the first locked position to a second position. Spring-lock mechanisms are well known in the art. It would have been obvious to one of ordinary skill in the art to substitute a spring-lock mechanism with the housing of Phillips such that it ensures that when the arm is positioned at the desired location the surgeon does not have to worry it will slip out and move during surgical use. Such a modification only involves routine skill in the art.

Claim 92 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ulrich DE (4201043). Ulrich is explained supra. However, Ulrich does not disclose having the cutout portions extend from the proximal end to a position near the distal end. It would

have been obvious to one of ordinary skill in the art to modify the length and location of the cutout in the guide of Ulrich since such a modification only involves routine skill in the art and would not affect the function of the apparatus.

Allowable Subject Matter

Claims 5-10,12,13,20,21,33-35,38 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 9/2/08 have been fully considered but they are not persuasive. Applicant argues with respect to the rejection of claims 86-90 over Santangelo that the pathways in the guide members are not in alignment with the distal end of the guide members. However, the Examiner respectfully disagrees since the pathways are just arbitrary space not defined by any structure in the claims. Santangelo clearly establishes pathways that are formed within the space of the guide members. As best understood the pathways are not required to be separate channels and thus it can be said from one portion or area bound by a wall of the guide member a pathway can be formed and at the tab area another pathway can be arbitrarily established also.

Regarding the rejection of claims 91-93 over the German patent, Applicants argue that the limitation of "opposed cut-out portions" defines two or more cut-outs.

However, the Examiner would like to inform the Applicants that first, the term "portion" does not establish any particular or distinct structure and thus it can be interpreted that a single cut-out has multiple "portions" that together define a whole or entire cut-out. Thus, Applicants arguments are not persuasive.

Applicant's arguments with respect to claims 1,26 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738